Hazardous Waste Pharmaceuticals

The Environmental Protection Agency (EPA) published “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine” in 2019. The rule established streamlined standards for handling hazardous waste pharmaceuticals while protecting human health and the environment. In February of 2022, the Vermont Hazardous Waste Management Regulations (VHWMR) adopted many of these standards into Subchapter 10. This fact sheet is intended to give guidance to healthcare facilities in Vermont that have questions regarding the management of hazardous waste pharmaceuticals.

Please note that hazardous waste pharmaceuticals in the healthcare sector have been managed under the hazardous waste regulations prior to the implementation of this pharmaceutical rule. The new rule changes how they are regulated and managed moving forward.

Definitions

- For the purposes of this fact sheet a “**pharmaceutical**” includes drugs for human or animal use, including prescription and over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, compounded drugs, investigational new drugs, as well as nicotine e-liquids packaged for retail sale and electronic nicotine delivery systems (e.g., e-cigarette or vaping pen).
- A “**hazardous waste pharmaceutical**” is a pharmaceutical that is a waste and exhibits one or more of the characteristics identified as hazardous in the VHWMR in §§ 7-205 through 7-208 or is listed in §§ 7-210 through 7-215. Please note that a pharmaceutical is not a waste if it is legitimately used/reused or reclaimed.
- A “**healthcare facility**” means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. Examples of healthcare facilities include hospitals, veterinary clinics, and pharmacies.
- A “**potentially creditable hazardous waste pharmaceutical**” means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in the original manufacturer packaging (except pharmaceuticals that were subject to recall), (2) undispensed, and (3) unexpired or less than one year past expiration date. This term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.
What parts of the new management standards apply to all healthcare facilities?

- All healthcare facilities are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through a publicly owned treatment works.
- Residues of hazardous waste pharmaceuticals in empty containers are no longer regulated as hazardous waste. Refer to VHWMR § 7-1008 for details.
- All healthcare facilities may send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Refer to VHWMR § 7-1010 for details.
- Over-the-counter nicotine replacement therapies (such as patches, gums, and lozenges) are no longer considered hazardous waste and do not need to be managed as such. Prior to the rule change, these wastes were managed as acute hazardous waste (waste code P075).

Does my healthcare facility need to notify the Secretary that it is operating under Subchapter 10?

- Healthcare facilities notified as small quantity generators (SQGs) or large quantity generators (LQGs) must notify the Secretary and operate under Subchapter 10.
- Healthcare facilities notified as very small quantity generators (VSQGs) have the option of notifying the Secretary and operating under Subchapter 10 or complying with the hazardous waste management standards for VSQGs.

Note: When determining your facility’s generator category, prior to opting into Subchapter 10, you must count both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. If your facility opts into Subchapter 10, then hazardous waste pharmaceuticals will not count towards your generator category.

How does my healthcare facility notify the Secretary that it is operating under Subchapter 10?

- Healthcare facilities must file a Hazardous Waste Handler Site Identification Form (EPA Form 8700-12) to notify the Secretary that they are operating under this subchapter.

After opting in, what does my healthcare facility need to do to comply with Subchapter 10?

- Pharmaceutical hazardous waste containers must be labeled with the words 'Hazardous Waste' and a description of the contents. 'Pharmaceuticals' is acceptable to use a descriptive. Generators must be able to document that they have accumulated the pharmaceutical hazardous waste for less than one year from the date it was generated. Dating the container is recommended to satisfy this requirement.
- Healthcare facilities must ensure that all personnel that manage hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures.
- Containers of non-creditable hazardous waste pharmaceuticals must be closed and secured, structurally sound, and compatible with their contents.
• A healthcare facility must ship non-creditable hazardous waste pharmaceuticals on a hazardous waste manifest and retain records for at least three years. This requirement does not apply to VSQG healthcare facilities.

• Potentially creditable hazardous waste pharmaceuticals may be shipped to a reverse distributor. Refer to VHWMR § 7-1004(e) and § 7-1010 for details.

• A healthcare facility shipping non-creditable hazardous waste pharmaceuticals on a manifest must write the word “PHRM” in Item 13. No other waste codes are required for non-creditable hazardous waste pharmaceuticals.

To view the entire Pharmaceutical Rule please review Subchapter 10: Hazardous Waste Pharmaceuticals of the VHWMR.

For more information regarding pharmaceutical hazardous waste, or if you have other hazardous waste management questions, please contact:

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